K063448

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Exihibit #2

510(K)Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirement of CFR 807.92

The assigned 510(k) number is :_____

1. Submitter's identifications :

EMG Technology Co. , LTD
4F-2, No.210 , 38RD., Taichung Industrial Park, Shituen Chiu, Taichung, Taiwan , R.O.C.
TEL : 886-4-23596033
FAX : 886-4-23596031

510(k) owner's name :
Mr. Roger Huang
General Manager

Contact person :
Sally Chuang
Email: Sally@emgtech.com.tw

2. Name of the Device :

Trade Name Including Model Number of Device :
EMG AC/DC Suction Unit , Model SUF01-XXX Series

Common Name or Classification Name : Powered Suction Pump

3. Information of the 510(k) Cleared Device(Predicate Device) :

DeVilbiss Suction Unit , Model 7305P-I
510(k) Number : K#982304

4. Device description :

The EMG AC/DC Suction unit is a compact medical suctioning device which can be powered by the AC current through a attached AC Adapter unit connecting to the wall electric outlet at home or DC power source through a set of built-in

rechargeable battery or automobile DC 14V electric power through power cord connecting to the receptacle during transportation.

The vacuum pressure of EMG AC/DC Suction unit is to be produced through a built-in vacuum pump which is consisted of DC motor, cylinder, piston connecting rod, cup seal, eccentric crank, inlet valve, outlet valve---etc parts. When turn on the suction unit, motor start to run, its shaft drive the eccentric crank which actuate the piston connecting rod moving up and down in the cylinder. When the piston is being in the down stroke, a vacuum pressure is produced in the cylinder, then air will be suctioned into the cylinder through an one way inlet port, when the piston is being in the up stroke, it pressed out these suctioned air through another one way outlet port to the atmosphere, these two one way port avoid air being suctioned from the atmosphere as well as air in cylinder being pressed back to the inlet port. When motor keep running, then a continuous vacuum pressure source through inlet port is produced.

One set of plastic cover enclose the vacuum pump, control p. c. board, battery and wire harness to protect user from electrical shock and mechanical hurt hazard. Following components on the cover are to be the operating interface to the use: a power switch, a receptacle, a vacuum adjusting set, vacuum meter and device vacuum inlet port. The vacuum adjusting set through inner tubing connecting to the inlet port of vacuum pump, the vacuum meter and the device vacuum inlet port are connecting to the vacuum adjusting set through a three way connector and inner tubing. Device's vacuum pressure can be adjusted by tuning the knob of vacuum adjusting set, accuracy within +/-5%. The vacuum meter display the vacuum pressure data during operation, the device vacuum inlet port provide the vacuum pressure source.

Connect the device vacuum inlet port, bacteria filter (Bacteria filter pore size: 0.2microns,Model:3928) and collection container with two PVC tubing respectively, then connect one end of a biocompatible patient tubing (comply with ISO10993 / material: PVC compound, Type: 3MSA060p3X) to the collection container inlet port, the other end of the patient tubing connected to the applied part (like drainage tubing). Put the applied part to the adequate location of patient body, then this device can start to carry out the suctioning sputum and other body liquid's operation.

The device is designed and manufactured to comply with UL60601-1 , CSA C22.2 No.601.1-M90 and IEC60601-1-2 EMC safety standards and meet the performance standard per ISO10079-1:1991

5. Intended Use :

The device is a vacuum suction device. It is to be used to remove infectious materials from wounds or fluids from a patient's airway or respiratory.
It is for use on the order of a physician only, and has the same intended use with the predicate Device DeVilbiss Suction Unit, Model 7305P-I.

6. The technological characteristics comparison to Predicate Devices :

The fundamental technological characteristics of the EMG AC/DC Suction Unit same as the predicate device DeVilbiss Suction Unit , Model 7305P-I.
For a complete technological characteristics comparison please refer Exhibit #5 .

7. Discussion of Non-Clinical Tests performed for Determination of Substantial Equivalence are follows :

The EMG AC/DC Suction Unit Compliance to the applicable voluntary standards include ISO10079-1 , IEC60601-1-1 and IEC60601-1-2 requirements .
It is same as the predicate device 510(k) summary statement .

8. Conclusion :

In terms of The EMG AC/DC Suction Unit have the same construction , function , safety and effectiveness and intended use as the 510(k) predicate device .
The EMG AC/DC Suction Unit is substantially equivalent to other legally market suction pumps used for this application .

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

EMG Technology Co., Ltd.
% Underwriters Laboratories, Inc.
Mr. Marc M. Mouser
Senior Project Engineer, Reviewer
2600 NW Lake Road
Camas, Washington 98607

NOV 3 0 2006

Re: K063448
Trade/Device Name: EMG AD/DC Suction Unit
Regulation Number: 21 CFR 878.4780
Regulation Name: Powered suction pump
Regulatory Class: II
Product Code: JCX
Dated: October 26, 2006
Received: November 15, 2006

Dear Mr. Mouser:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

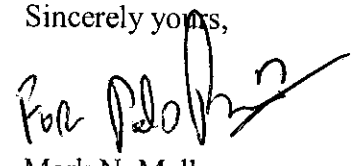
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K063448

Indications for Use

510(k) Number (if known):

Device Name: EMG AC/DC Suction Unit

Indications For Use:

The device is a vacuum suction device. It is to be used to remove infectious materials from wounds or fluids from a patient's airway or respiratory.
It is for use on the order of a physician only.

Prescription Use ✓ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K063448